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OFFICE OF  
PESTICIDES AND TOXIC  
SUBSTANCES

MEMORANDUM

**SUBJECT:** New Use Patterns for Zinc Omadine.

EPA ID# 001258-00840 Project No. 0-1883  
Case Nos. 029309, 037356 Tox. Chem. No. 923

**FROM:** John E. Whalan, D.A.B.T., Toxicologist  
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4-23-91

**TO:** John Lee (PM Team #31)  
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**THRU:** Roger L. Gardner, Section Head  
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Health Effects Division (H7509C)

*Roger L. Gardner*  
4-23-91 KB  
5/9/91

I. Background:

Olin Chemicals has requested the addition of the following new uses for two zinc omadine formulations.

Zinc Omadine® Powder Industrial Microbiostat (which contains 95% zinc 2-pyridinethiol-1-oxide). The supplemental labels, which carry the signal word "Danger," described these uses as follows:

1. "To inhibit the growth of bacteria and fungi in dry wall and other gypsum, perlite, plaster-like or mineral based building materials used in the manufacture of ceilings, ceiling tiles, walls and partitions, etc.
2. "For the in can preservation of clay, mineral, pigment and guar gum slurries, latex emulsions and similar high-solids aqueous media used in non-food & non-medical applications."
3. "For the dry film preservation of natural and synthetic adhesives, caulks, patching compounds, sealants, and grouts."
4. "For the dry film preservation of aqueous latex architectural paints and coatings."

Zinc Omadine® 48% Aqueous Dispersion Industrial Microbiostat (which contains 48% zinc 2-pyridinethiol-1-oxide). The supplemental labels, which carry the signal word "Danger," described these uses as follows:

1. "To Inhibit the Growth of Bacteria and Fungi in Dry Wall and Other Gypsum, Pearlite, Plaster-like or Mineral Based Building Materials Used in the Manufacture of Ceilings, Ceiling Tiles, Walls & Partitions, etc."
2. "For the In Can Preservation of Clay, Mineral, Pigment and Guar Gum Slurries, Latex Emulsions & Similar High-Solids Aqueous Media Used in Non-Food & Non-Medical Applications."
3. "For the dry film preservation of natural and synthetic adhesives, caulks, patching compounds, sealants, and grouts."
4. "For the dry film preservation of aqueous latex architectural paints and coatings."

There are thirteen registered use patterns for zinc omadine. According to the Data Call-In Notice for Antimicrobials (William L. Burnam memorandum, March 31, 1987), all of these uses are in the Low Exposure Category except for metalworking cutting fluids which is in the High Exposure Category.

The proposed new use patterns will result in extensive distribution in household, commercial, industrial, and institutional sites, but the product will be bound to substrates and thus will not result in undue human exposure. The Exposure Category for these uses is considered to be Low. Data requirements for a Low Exposure Category use include an acute battery, 90-day dermal, 90-day inhalation, developmental toxicity in two species, and a mutagenicity battery. These are all data gaps.

## II. Recommendation:

The data base for zinc omadine is seriously deficient. During the recent FIFRA 88 review of zinc omadine, the Registrant recognized this fact, and proposed using surrogate data for an analog - sodium omadine. This recommendation is without merit because the data base for this chemical is equally deficient. HED cannot recommend any new uses for zinc omadine until sufficient acceptable data are available to describe its toxicologic character.

III. Data Requirements (CFR §158.35):

REGISTERED USE PATTERNS: Siding, metalworking cutting fluids, PVC plastics, PVC plastics (non-food contact surfaces), PVC tarpaulins, vinyl, shower curtains, synthetic polymers, vinyl wall coverings, vinyl coated fabrics, vinyl swimming pool liners, awnings, and tents.

Technical: Registration Nos. 1258-840, 1258-841 (purity unknown)

Required/Satisfied

|       |      |   |   |
|-------|------|---|---|
| 81-1  | Y    | N | Acute Oral Toxicity                       |
| 81-2  | Y    | N | Acute Dermal Toxicity                     |
| 81-3  | Y    | N | Acute Inhalation Toxicity                 |
| 81-4  | Y    | N | Primary Eye Irritation                    |
| 81-5  | Y    | N | Primary Dermal Irritation                 |
| 81-6  | Y    | N | Dermal sensitization                      |
| 81-7  | N    |   | Acute Delayed Neurotoxicity (hen)         |
| <hr/> |      |   |   |
| 82-1  | H*   | N | Subchronic Oral (rodent)                  |
| 82-1  | N    |   | Subchronic Oral (nonrodent)               |
| 82-2  | H*   | N | 21-Day Dermal                             |
| 82-3  | L*   | N | 90-Day Dermal                             |
| 82-4  | N    |   | 21-Day Inhalation (tobacco use)           |
| 82-4  | L*   | N | 90-Day Inhalation                         |
| 82-5  | N    |   | 90-Day Neurotoxicity (hen)                |
| 82-5  | N    |   | 90-Day Neurotoxicity (mammal)             |
| <hr/> |      |   |   |
| 83-1  | H*   | N | Chronic Toxicity (rodent)                 |
| 83-1  | H*   | N | Chronic Toxicity (nonrodent)              |
| 83-2  | H*   | N | Carcinogenicity (two species)             |
| 83-3  | H,L* | N | Developmental Toxicity (first species)    |
| 83-3  | H,L* | N | Developmental Toxicity (second species)   |
| 83-4  | H*   | N | Reproduction                              |
| 83-5  | N    |   | Chronic/Carcinogenicity (see 83-1 & 83-2) |
| <hr/> |      |   |   |
| 84-2  | H,L* | N | Mutagenicity - Gene Mutation              |
| 84-2  | H,L* | N | Mutagenicity - Structural Chrom. Aberr.   |
| 84-2  | H,L* | N | Mutagenicity - Other Genotoxic Effects    |

|       |    |   |                        |
|-------|----|---|------------------------|
| 85-1  | H* | Y | General Metabolism     |
| 85-2  | N  |   | Dermal Penetration     |
| ..... |    |   |                        |
| 86-1  | N  |   | Domestic Animal Safety |

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\* Required studies for High Exposure Category (H) and/or Low Exposure Category (L), based on the Bill Burnam Memorandum on Data Call-In Notices for Antimicrobials (March 31, 1987).

Y - Yes  
N - No

W - Waived  
P - Partially

IV. Toxicology Profile:

Technical: Registration No. 1258-840, 1258-841 (purity unknown)

|      | STUDY  | RESULTS   |
|------|--|---|
| 81-1 | Acute Oral   | Data Gap  |
| 81-2 | Acute Dermal   | Data Gap  |
| 81-3 | Acute Inhalation   | Data Gap  |
| 81-4 | Primary Eye Irritation   | Data Gap  |
| 81-5 | Primary Dermal Irritation  | Data Gap  |
| 81-6 | Dermal Sensitization   | Data Gap  |
| 82-1 | 3-Month Feeding, Rat<br><b>Supplementary</b><br>Document No. 3933  | NOEL = 15 ppm<br>LEL = 75 ppm (increased organ body weights for liver, kidney, and testes; decreased survival, hind limb weakness). |
| 82-2 | 21-Day Dermal  | Data Gap  |
| 82-3 | 90-Day Dermal  | Data Gap  |
| 82-4 | 90-Day Inhalation  | Data Gap  |
| 83-1 | Chronic Feeding, Rodent  | Data Gap  |
| 83-1 | Chronic Feeding, Nonrodent   | Data Gap  |
| 83-2 | Carcinogenicity, Two species                                       | Data Gap  |
| 83-3 | Developmental Toxicity, Rat<br>Invalid<br>Document Nos. 3935, 3022 | This IBT study was invalidated.   |

|      |   |   |
|------|---|---|
| 83-3 | Developmental Toxicity<br>(dermal), Pig<br>Invalid<br>Document No. 3933                                     | <b>This IBT study was invalidated.</b>  |
| 83-3 | Developmental Toxicity,<br>Rabbit<br>Minimum<br>Document No. 3933   | <b>NOTE: This IBT study is probably not acceptable because no maternal toxicity was induced at the two doses tested (1.0 and 2.5 g/kg).<br/>Maternal NOEL &gt;2.5 g/kg<br/>Developmental NOEL &gt;2.5 g/kg (HDT)<br/>Reproductive NOEL &gt;2.5 g/kg (HDT)</b> |
| 83-4 | Reproduction  | <b>Data Gap</b>   |
| 84-2 | Gene Mutation   | <b>Data Gap</b>   |
| 84-2 | Structural Chromosome<br>Aberration - Dominant<br>Lethal Test, Mouse<br>Invalid<br>Document Nos. 3935, 3021 | <b>This IBT study was invalidated.</b>  |
| 84-2 | Other Genotoxic Effects   | <b>Data Gap</b>   |
| 85-1 | Metabolism, Pig<br>Minimum<br>Document No. 3933   | Significant bioretention and accumulation in renal hepatic and pancreatic tissues.  |

V. Data Gaps:

Data requirements that have not been satisfied for High Exposure Category uses include an acute battery, subchronic feeding, 21-day dermal, chronic feeding in rodent and nonrodent, carcinogenicity in two species, developmental toxicity in two species, reproduction, and a muta-genicity battery.

Data requirements that have not been satisfied for Low Exposure Category uses include an acute battery, 90-day dermal, 90-day inhalation, developmental toxicity in two species, and a mutagenicity battery.

VI. Action Taken to Obtain Additional Information or Clarification:

These data base deficiencies were identified by the Registrant and HED in the course of FIFRA 88 review.

VII. Reference Dose (RfD):

No RfD has been defined.

VIII. Pending Regulatory Actions:

There are at this writing no pending regulatory actions against the Registration of this pesticide.

IX. Toxicologic Issues Pertinent to Granting this Request:

There are insufficient data available to allow a judgment on this petition.